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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,065	02/08/2005	Takaya Sugawara	KPO-TSC-P1/TK-80/US	4447
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OSTRAGER CHONG FLAHERTY & BROITMAN PC 570 LEXINGTON AVENUE FLOOR 17 NEW YORK, NY 10022-6894			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 12/10/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/524,065	<b>Applicant(s)</b> SUGAWARA ET AL.	
	<b>Examiner</b> MELISSA S. MERCIER	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Change of Examiner***

The examiner assigned to the instant application has changed. The new examiner is Melissa Mercier. Contact information is provided at the end of this Office Action.

### ***Summary***

Receipt of Applicants Remarks and Amended Claims filed June 29, 2009 is acknowledged. Claims 8-11 are pending in this application. Applicant has cancelled claims 1-7.

### ***Withdrawn Objections/Rejections***

#### ***Drawings***

The objection to the drawings under 37 CFR 1.83(a) for not showing every feature of the invention specified in the claims has been withdrawn in view of Applicants amendment to the claims to require only 2 layers in the backing layer, which is shown in the drawings.

#### ***Specification***

The objection to the specification for failing to provide proper antecedent basis for the claimed subject matter is withdrawn in view of Applicants persuasive arguments regarding the nature of the laminate structure in the remarks filed on June 29, 2009.

***Claim Rejections - 35 USC § 112***

The rejections of claims 6-9 under 35 USC 112, first and second paragraphs, for written description and indefiniteness, respectfully, has been withdrawn in view of Applicants amendments to the claims to clarify the backing layer construction.

***Claim Rejections - 35 USC § 103***

The rejection of claims 6 and 9/6 under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. (US 6,177,098) in view of Akemi et al. (US 5,242,951 ) has been withdrawn in view of Applicants cancellation of claim 6.

The rejection of claim 8/6 under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. in view of Akemi et al. and further in view of Radloff et al. (WO 2002/038134). US 2004/0091521 will be used herein as an English equivalent translation of WO 2002/038134 has been withdrawn in view of Applicants cancellation of claim 6.

The rejection of claims 6 and 9/6 under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Kawaji et al has been withdrawn in view of Applicants cancellation of claim 6.

The rejection of claim 8/6 under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Kawaji et al. and further in view of Radloff et al. has been withdrawn in view of Applicants cancellation of claim 6.

The rejection of claims 7 and 9/7 under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 5,693,335) in view of Hoffmann et al. (US 5,393,529) and further in

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view of Muraoka et al. (US 5,876,745) has been withdrawn in view of Applicants cancellation of claim 7.

The rejection of claim 8/7 under 35 U.S.C. 103(a) as being unpatentable over Xia et al. in view of Hoffmann et al. and further in view of Muraoka et al. and further in view of Radloff et al. has been withdrawn in view of Applicants cancellation of claim 7.

### ***Newly Applied Rejections/Objections***

#### ***Claim Objections***

Claim 9 is objected to because of the following informalities: Claims 10-11 are already limited to an acrylic pressure sensitive adhesive. It is suggested that Applicant amend claim 9 to recite "wherein the acrylic component of the acrylic pressure sensitive adhesive is selected from at least one of the following..." in order to clarify the claim language.

Claims 10-11 are objected to because of the following informalities: claims 10-11 recite "wherein the adhesive layer further comprises..." No components of the adhesive layer are previously set out in order to necessitate the recitation of "further comprises" therefore it is suggested Applicant remove "further" to clarify the claim language.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. (US 6,177,098) in view of Akemi et al. (US 5,242,951 ).

With respect to claim 6, Kawaji et al. discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the backing is a laminate structure comprising a polyethylene terephthalate film and a non-woven fabric (col. 3, lines 25-33, 52-54). Kawaji et al. further discloses the polyethylene terephthalate film has a thickness of 1.6 - 6.0 um (col. 3, lines 48-55). Kawaji et al. further discloses the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive comprising 2-ethylhexyl acrylate, estradiol, crotonamite and oleic acid (example 2) in the claimed ranges.

Kawaji et al. further discloses using isocyanate-based cross linking agents (col. 4, lines 52-53), however fails to expressly disclose the content amount of the isocyanate-based crosslinking agent. Additionally, Kawaji et al. fails to expressly disclose the specific thickness of the non-woven fabric, however discloses the non-woven fabric has an appropriate thickness (col. 3, lines 27-33).

Akemi et al. teaches using 0.01-2% of an isocyanate-based crosslinking agent (col. 5, lines 17-18, 33-35), and more specifically in Example 3, 0.2% of an isocyanate-based crosslinking agent. It would have been obvious to one of ordinary skill in the art to modify the amount of crosslinking agent used in order to provide the desired aging time of the pressure-sensitive adhesive layer (col. 5, lines 30-32). Akemi et al. also teaches a

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backing having a laminate structure comprising a polyester film having a thickness of 1-25 um and a porous film having a thickness of 1-200 um (col. 2, lines 54-65).

It would have been obvious to one of ordinary skill in the art to modify the thickness of the non-woven fabric in order to prevent diffusion of the drug and maintain good handling properties, as desired (Kawaji: col. 3, lines 27-33). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. in view of Akemi et al. and further in view of Radloff et al. (WO 2002/038134). US 2004/0091521 will be used herein as an English equivalent translation of WO 2002/038134.

The combination of Kawaji and Akemi are discussed above and applied in the same manner.

The combination however, fails to disclose the flexible polymer film being a low density polyethylene.

Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060]. It would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Akemi et al. to be that of Radloff et al. in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

**\*the laminate structure of Kawaji is different from that of the instant claims.**

The Examiner respectfully disagrees. The patch, as disclosed in the Examples, comprises the adhesive layer being applied to silicon treated polyester film, which is not the terephthalate polyester. The silicon polyester film is then layered with the laminated backing layer, which is a nonwoven fabric and the polyester terephthalate as recited in the instant claims.

Applicant has elected not to discuss the secondary references at this time.

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 5,693,335) in view of Hoffmann et al. (US 5,393,529) and further in view of Muraoka et al. (US 5,876,745).

Xia et al. discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive containing a cross linking agent, 0.5-10% by weight of isopropyl myristate as a distribution coefficient control agent (skin permeation enhancer) and 0.2-6% of norethindrone (equivalent to norethisterone) as an active ingredient (col. 2, lines 17-27, 34-59; col. 3, lines 28-30, 39-50), therefore the content amount of the ingredients can fall in the claimed range. It would have been obvious to one of ordinary skill in the art to modify the quantity for each ingredient in order to



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optimize the desired medicinal benefits. Further, it has been held that discovering an optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Xia et al. also discloses examples of the crosslinking agents used are in Hoffman et al.

Hoffman et al. discloses norethisterone-containing transdermal systems utilizing isocyanate-based crosslinking agents (col. 3, lines 43-54; col. 5, line 55). However, Xia et al. fails to expressly disclose the amount of crosslinking agent used. Muraoka et al. teaches it is well known to utilize 0.35% of an isocyanate-based crosslinking agent (Examples 2 and 8). It would have been obvious to one of ordinary skill in the art to modify the crosslinking agent to be isocyanate-based in order to provide the desired reactivity and handling properties (col. 5, lines 1-25).

Xia et al. further discloses the backing is a laminate structure comprising one or more polymer layers and metal foil, wherein the polymer is polyethylene terephthalate (col. 3, lines 39-50), however fails to expressly disclose the polyethylene terephthalate film having a thickness of 0.1-10 um and the inclusion of a flexible polymer film or a woven or nonwoven fabric having a thickness of 1-200 um.

Muraoka et al. discloses an external patch with a backing (support) having a laminate structure comprising a polyester film having a thickness of 0.1-10 um and a woven or nonwoven fabric having a thickness of 1-200 um (col. 6, lines 25-66). It would have been obvious to one of ordinary skill in the art utilize the laminate structure of Muraoka et al. in order to provide an improved anchoring effect (col. 7, lines 39-47; col. 1, line 58 - col. 2, line 5).

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With respect to claim 9 the modified Xia et al. discloses the acrylic pressure-sensitive adhesive comprises 2-ethylhexyl acrylate (col. 2, line 41).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. in view of Hoffmann et al. and further in view of Muraoka et al. and further in view of Radloff et al.

The combination of Xia and Hoffman is discussed above and applied in the same manner.

The combination does not disclose the flexible polymer film being a low density polyethylene.

Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060].

It would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Xia et al. to be that of Radloff et al. in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

### ***Response to Arguments***

Applicants did not provide any arguments regarding the Xia in view of Hoffman and Muraoka.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

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(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615